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DOCKET NO. 37972

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: The Salk Institute)
For Biological Studies)
)
Patent No.: 4,244,946)
)
Issue Date: January 13, 1981)
)
Title: WATER-SOLUBLE PEPTIDES)
AFFECTING GONADAL FUNCTION)

LETTER

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Box PAT. EXT.

Attention: Charles E. van Horn

Dear Sir:

An Application for Extension of the Term of the above-identified U.S. Patent was duly filed on February 21, 1992, and the undersigned has now received a copy of the letter over the signature of Stuart L. Nightingale indicating that the FDA had determined an applicable review period for SUPPRELIN. Applicant has objected to the basis upon which the period was determined and has filed a Petition for Reconsideration, a copy of which is

attached hereto. It is believed that the period was improperly extended by including an initial review period for treatment of a totally unrelated medical indication, namely endometriosis, as set forth in the attached petition.

It is respectfully requested that the United States Patent and Trademark Office defer action on the Application for Extension of Patent Term until the FDA has taken action on this Petition for Reconsideration.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

By: _____
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Registration No. 20,856

April 15, 1994

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VIA EXPRESS MAIL

April 1, 1994

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

Petition for Reconsideration

RE: Docket No. 92E-0133 - Supprelin
Application for Patent Term Extension
Our File No. 37972 (3052)

Dear Sir:

Reconsideration is petitioned with respect to the denial of the Request for Redetermination of the period for the testing phase of Supprelin, as set forth in the letter of Stuart L. Nightingale, M.D. dated March 8, 1994.

It is believed that the FDA, in determining such a testing period for purposes of patent term extension, has decided to formulate an overall procedure to be followed in all cases in order to avoid having to make individual determinations based upon an assessment of the facts in each particular case. While it is acknowledged that such a procedure would ease the administrative burden on the FDA, it is submitted that justice is not done in the present case when the facts of the situation are ignored with respect to the regulatory review period for

Supprelin prior to permitting its marketing for the treatment of precocious puberty. Attached is a copy of our July 16, 1992, Request for Redetermination, reconsideration of the denial of which is hereby petitioned.

We wish to emphasize that the regulatory review period in question is that particular regulatory review pertinent to the first permitted commercial marketing or use of the product as set forth in 35 U.S.C. §1.156(a)(5)(A). It is specifically pointed out in 35 U.S.C. §1.156(c) that the patent term shall be extended "by the time equal to the regulatory period for the approved product", and it is clear that the product was approved for treatment only of precocious puberty--not for treatment of endometriosis. It is perfectly clear that the class of patients suffering from precocious puberty is totally different from the class of patients suffering from endometriosis; therefore, the response of patients taking part in a clinical study for treatment of endometriosis would be in no way relevant with respect to treatment for the indication of precocious puberty.

The unwarranted extension of the regulatory period to include the time when there was an investigation by a different investigator for a totally different indication, i.e. endometriosis, results (under the peculiar circumstances of the present case) in unfairly shortening the patent term extension. It thus works to the considerable detriment of the patentee, The Salk Institute for Biological Studies, a well-known, not-for-profit organization.

In view of the foregoing, this petition is being filed for reconsideration by the F.D.A. of the denial of Salk's request to limit the regulatory review periods to those when investigation was proceeding with regard to the only indication for which regulatory approval has been given, namely the use for treatment of precocious puberty. A redetermination of the period of the testing phase to constitute the time period from about

December 24, 1984, through May 23, 1989, i.e. about 1,609 days, is respectfully requested.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY for
THE SALK INSTITUTE FOR BIOLOGICAL STUDIES

By: James J. Schumann

Enclosure

JJS/lm

bcc: D. Dale Busch (w/o encl)
Joseph J. Brindisi (w/o encl)